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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HELLER EHRMAN WHITE & MCAULIFFE LLP
1717 RHODE ISLAND AVE, NW
WASHINGTON, DC 20036-3001

EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,344	LAW, PETER K.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/05 has been entered.

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection under 35 USC 103 is hereby withdrawn upon further consideration of the cited prior art, the amendments, and Applicant's arguments in the replies. The fundamental question of whether the cited references would necessarily lead one of ordinary skill in the art to the claimed invention has not been adequately addressed. Wu describes implanting a specific type of endorphin producing pituitary tumor cell line, not myoblast, into the spinal cord, not into muscle or fat tissue. Beutler describes transfecting fibroblasts, not myoblasts, with an endorphin transgene and implanting the fibroblasts into the spinal cord or brain, not muscle or fat tissue. While these references demonstrate the interest in the art on using opioid-expressing cells to treat chronic pain, they would not have suggested using myoblasts or implanting the opioid producing

cells into muscle or fat. Deglon teaches transfecting myoblasts with CSF, not an opioid, and encapsulating them and implanting the capsule into the brain, not into muscle or fat. This reference only shows that myoblasts had been considered as a cell type to use for delivering encapsulated cells to the central nervous system, not to muscle and not as a suspension. Law describes the administration of normal myoblasts, i.e. that express dystrophin, to muscular dystrophy patients in hopes of regenerating some normal muscle in these patients. None of these references taken alone or in combination would have led one of ordinary skill in the art to the claimed invention, which requires that autologous or allogeneic myogenic cells be transfected with a gene encoding an opioid, and delivered as a suspension to muscle or fat.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 42 recites the term "allogenic". This term does not appear in the specification. It is suggested that page 9, lines 18-22, be amended to introduce the term where myoblasts obtained from humans other than the human patient is discussed.

Claim Objections

Claims 52, 53, 61, and 62 are objected to because of the following informalities: In part (a) of each of claims 52 and 61, the phrase "preparing pure in vitro culture" is improper grammar

and "in vitro" should be in italics in claims 52, 53, 61, and 62, and should be replaced with -- preparing a pure *in vitro* culture--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53 and 61-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 53 and 62 recite "satellite cell," in contrast to previous claims reciting satellite myoblast cells (e.g. original claim 6), which are described originally. Applicant has not indicated where the specification supports broadening the scope of this term by deleting "myoblast". The term "satellite cell" has been applied to other cell types, such as perineuronal satellite cells (glial cells) that also occur in muscle, and the original specification describes only "satellite myoblast cells". This part of the rejection would be overcome by insertion of --myoblast-- between "satellite" and "cells".

Claim 61, and dependent claims, recite that the cells are to be introduced "into a region that contains fat cells in a form that allows fusion with …pre-existing … fat cells." Applicant has not pointed to where the original disclosure supports introducing the cells into "into a region that

contains fat cells" or "in a form that allows fusion with ...pre-existing ... fat cells." The original specification describes that the transfected myogenic cells are "injected into adipose tissue" or "implanted in ... adipose tissue" where they will be "converted into fat cells" (spec., page 7, lines 1-8, 27-32; page 13, lines 11-13). No mention is made of introducing the cells "into a region that contains fat cells" as opposed to directly into adipose tissue or that the cells would be "in a form that allows fusion with ...pre-existing ... fat cells" as opposed to simply differentiating into fat cells.

Claims 52-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method wherein myoblasts are the myogenic cells, does not reasonably provide enablement for other types of myogenic cells, such as myotubes or muscle fibers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 61-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method wherein myoblasts are the myogenic cells, does not reasonably provide enablement for other types of myogenic cells, such as myotubes or muscle fibers, or for myogenic cells that are suspended in a form that allows fusion with fat cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to the use of a generic myogenic cell, which the specification teaches includes myoblasts, myotubes and muscle fibers (page 5, lines 3-5; page 9, lines 1-3).

The specification teaches the isolation and expansion of satellite myoblast cells or myoblasts from muscle tissue, but does not teach how one would "culture", much less produce a "pure culture," of myotubes or muscle fibers or how one would successfully introduce the latter into muscle or fat cells such that they would fuse with either pre-existing muscle cells or pre-existing fat cells as required by the claims.

Skuk (Expert Opin. Biol. Ther. 4 (12): 1871-1875, 2004) reviews the state of the art of myoblast transplantation therapy from before the time the instant invention was made until long after it was made. Skuk discloses (pages 1873-74, sections 3 and 3.1) that myotubes or muscle fibers are "useless for transplantation" because they "cannot be cultured or properly delivered." Furthermore, Skuk discloses that myoblasts "are the only the only donor cells that are capable of producing significant expression of donor proteins in skeletal muscle of … humans."

In view of the lack of guidance on the culturing and use of myogenic cells other than myoblasts in the specification, and evidence that those in the art were unaware of how one might culture other types of myogenic cells or implant them in muscle or fat to accomplish the goals of the method, undue experimentation would clearly have been required to practice the invention with myogenic cells other than myoblasts.

Claims 61-70 explicitly require that the cells be "in a form that allows fusion with … pre-existing … fat cells". As indicated above, this is new matter, and thus the specification clearly lacks guidance as to how to prepare the cell suspension in a form that would allow fusion with fact cells of the patient. Furthermore, Satoh et al. (Transplant. Proc. 24(6): 3017-3019, 1992) describes the implantation of myoblasts into adipose tissue. Rather than fusing with fat cells or even differentiating into fat cells, as suggested in the specification, the implanted myoblasts

differentiated into myotubes. Thus, if it is in fact possible to make a suspension of myogenic cells in a form that would allow fusion with fat cells (or even allow differentiation of myoblasts into fat cells), more would be required than is taught in the specification, and the prior art of record teaches away form that possibility. Consequently, one of skill in the art would have to engage in undue experimentation just to determine whether such a thing is possible, much less how to prepare such a suspension.

Claims 61-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 recites the limitation "the myogenic cells" in part (b), and the limitation " the human patient" at the end of part (c). There is insufficient antecedent basis for these limitations in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER